nucleotide sequence of SEQ ID NO:35 and complementary sequences thereof.

60. (New) The kit of claim 57 wherein the probe or primer comprises a nucleotide sequence of SEQ ID NO: 33 and complementary sequences thereof.

61. (New) The kit of claim 57 wherein the probe or primer comprises a nucleotide sequence of SEQ ID NO: 35 and complementary sequences thereof.

62. (New) A kit according to claim 16 which comprises a first primer which is selected from the group consisting of SEQ ID NOS: 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, and 126 and a second primer which is selected from the group consisting of SEQ ID NOS: 45, 47, 49, 51, 53, 55, 57, 59, 61, 63, 65, 67, 69, 71, 73, 75, 77, 79, 81, 83, 85, 87, 89, 91, 93, 95, 97, 99, 101, 103, 105, 107, 109, 111, 113, 115, 117, 119, 121, 123, 125, and 127.

REMARKS

This submission is in response to the Restriction Requirement dated July 1, 2002. At the outset, Applicants would like to thank Examiner Wilder for taking time for an informal interview with Applicants' representatives to help clarify

the Action.

Claims 54-62 have been added, two paragraphs of the specification have been amended, claims 44-53 have been cancelled, without prejudice, and a substitute Figure 4 has been submitted for reasons explained in greater detail below. By way of this amendment, claims 1-44 and 53-62 are pending. A courtesy copy of the pending claims is attached. Reconsideration of the above identified application, in view of the above amendments and the following remarks, is respectfully requested.

Amendments to Specification:

The amendments to the specification have been made for purely formal reasons and do not add new matter. The changes made to the paragraph spanning lines 10-19 of page 111 of the specification (changing "column 5" to "column 6" and "column 6" to "column 7" on line 16) were made to amend typographical errors. It is clear in Figure 4 (both in the originally submitted Figure 4 and the substitute Figure 4 submitted herewith) that it is columns 6 and 7, not columns 5 and 6, of Figure 4 that list the location and length, respectively, of the primers listed in Figure 4. Applicants respectfully point out that the column number is based on column headings, e.g. "SEQ ID NOS" heads column 5 and "Location" heads column 6. Therefore, Applicants assert that no new matter has been added by way of this Amendment and respectfully request that this amendment to the

specification be entered.

The changes made to the paragraph spanning lines 17-28 of page 115 of the specification (changing disc02a to disc03a on lines 21 and 25 of page 115) were made to amend typographical errors. These amendments are supported by the specification; the SNPs listed on line 21 of page 115 of the specification are referred to as being in Table 6A, which lists disc03a, not disc02a. In addition, the SNPs referred to on line 25 of page 115 are referred to on line 28 as those listed in Table 6B, which lists disc03a, not disc02a. Therefore, Applicants assert that no new matter has been added by way of this Amendment and respectfully request that this amendment to the specification be entered.

This Amendments to the specification do not change the scope of the claims and entry of this Amendment will not require any substantial additional work by the PTO.

Correction of Drawing

Applicants request that original Figure 4 be cancelled and substituted with Figure 4 submitted herewith. Upon review of the SEQ ID NOS listed in Figure 4, it was determined that the SEQ ID NOS did not correspond to the sequences listed. Therefore, Figure 4 has been amended such that the correct SEQ ID NOS are listed next to their respective primers. This amendment does not constitute new matter and is purely typographical in nature, a fact supported by the following

sections of the specification: page 7 lines 5-7 (description of Figure 4), page 38 lines 27-28, page 39 lines 4-6, page 40 lines 20-21, page 102 line 1, and the Sequence Listing. Therefore, Applicants assert that no new matter has been added by way of this substitute figure and respectfully request that originally filed Figure 4 be replaced with substitute Figure 4.

Restriction Requirement

The Examiner has required restriction to one of the following groups of claims under 35 U.S.C. §121:

I. Claims 1-20, drawn to an isolated nucleic acid and kit.

II. Claims 21-43, drawn to a method of detecting a DISC1 allelic variant.

III. Claims 44-53 drawn to a method of treating a subject with disease.

The Examiner also alleges that SEQ ID NOS: 1, 4 and 33-127 are patentably distinct sequences and thus has required election of one disclosed reference sequence (SEQ ID NO: 1 and SEQ ID NO: 4) and one sequence from the group consisting of SEQ ID NOS: 33-127.

In order to be fully responsive to the Requirement for Restriction, Applicants hereby provisionally elect, with traverse, to prosecute claims 1-20, corresponding to the claims of Group I, and reference sequence SEQ ID NO: 1 and SEQ ID NO: 33. New claims 54-62 have added and have subject matter that falls

within the elected subject matter.

Applicants respectfully traverse the Requirement for Restriction and reserve the right to petition therefrom under 37 C.F.R. § 1.144. In particular, Applicants respectfully request reconsideration of the Restriction Requirement or, in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group and more than one species of SNP sequence.

I. **Groups I and II Should be Examined Together**

Applicants believe that Groups I and II should be examined together pursuant to 35 U.S.C. §103(b)(2), under which a patent issued on a biotechnological process shall also contain claims directed towards the composition of matter utilized by that process. 35 U.S.C.§103(b) mandates that "a biotechnological process (in the present case, detecting DISC1 allelic variants) using or resulting in a composition of matter that is novel under Section 102 and nonobvious under Section 103(a) shall be considered non-obvious if claims to the process and the composition of matter are contained in .... the same application for patent ..." 35 U.S.C.§103(b)(1)(A). Using the novel products of Group I in any process requires determining the novelty of the products of Group I. Once the novelty of these products is established, methods of using these products are patentable. *In re Ochiai*, 37 USPQ 2d. 1127 (Fed. Cir.1995). Thus even if the process of using the nucleic acids represents patentably distinct subject matter, this subject matter should nevertheless be considered with the product claims.

Under Patent Office examining procedures, "if the search and examination of an entire application can be made without serious burden, the Examiner ***must*** examine it on the merits, even though it includes claims to distinct or independent inventions." See, M.P.E.P. § 803 (emphasis added). The groups of claims designated by the Examiner (*i.e.*, Groups I and II, *supra*) do not, however, define products and methods for using such products with biological properties which are distinct or which warrant separate examination and searches. Rather, the claims represent a web of knowledge and continuity of effort that merits examination in a single application. The conjoint examination and inclusion of all of the claims of groups I and II (*i.e.*, claims 1-43) in the instant application is therefore appropriate and would not present an undue burden on the Examiner.

II. The Election of a Nucleic Acid is Properly a Species Election

The Examiner contends that SEQ ID NOS:1, 4, and 33-127 are patentably distinct sequences, and therefore subject to restriction. SEQ ID NO:1 is a cDNA sequence which encodes a DISC1 polypeptide (see page 7, line 10 to page 9, line 2 of the specification.). SEQ ID NO:4 is a large, genomic DNA clone (BAC) that contains a genomic sequence for a segment of human chromosome 1 which contains DISC1 and DISC2, referred to as "zlhXdisc43" or "disc43" (see page 107, lines 1-15 of the specification). Each of SEQ ID NOS:33-43 represent a single nucleotide polymorphism, ten nucleotides 5', and ten nucleotides 3' to that

particular variant nucleotide of the DISC1 sequence of SEQ ID NO:1 (see Table 5B on page 114 of the specification.). SEQ ID NOS:44-127 represent oligonucleotide primers used to amplify DISC1 and DISC2 genomic sequences (see Figure 4, described on page 110, lines 9-11 of the specification). Were these unrelated sequences, such as ESTs from a genome sequencing project, Applicants might agree that the Examiner's requirement for a sequence election is proper. However, the sequences of SEQ ID NOS:33-43 represent variants of DISC1, and therefore present a species-genus relationship. It bears repeating that the SNP sequences of the present invention are extracts, i.e., local views, of DISC1 allelic variants, and therefore, are not sequences unrelated to DISC1. Accordingly, Applicants assert that it would not present an undue burden on the Examiner to examine more than one sequence of the sequences of SEQ ID NOS:33-127, particularly SEQ ID NOS:33 and 35. SEQ ID NOS:33 and 35 are SNPs of DISC1 and therefore are merely variants of DISC1. In fact, since these SNPs only differ from one another by one nucleotide; searching for two of these SNPs would not require any additional work on the part of the Examiner as compared to searching for one SNP.

Indeed, after establishing patentability of the elected DISC1 SNP (represented by SEQ ID NO:33), the Examiner must consider patentability of the generic claim. To properly discharge this function, the Examiner must search for other SNPs. In so doing, the Examiner may and should consider the SNPs recited in the claims. For this reason, Applicants are entitled to consideration of a reasonable

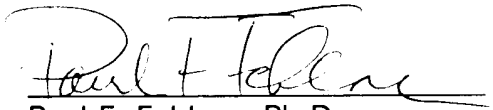
number of species of DISC1 allelic variants (the new claims select two, the elected species of DISC1 variant containing SEQ ID NO:33, and another containing SEQ ID NO:35). See 37 CFR § 1.141(a).

By reason of the foregoing, applicants believe that the restriction between species of DISC1 alleles is improper and should be withdrawn in favor of a species election requirement. Applicants' election of SEQ ID NO:1 and SEQ ID NO:33 should thus be treated as a species election.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of this application. In view of the above remarks, withdrawal or modification of the Requirement for Restriction is respectfully requested, and an early action on the merits is courteously solicited.

Respectfully submitted,



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